JUL 1 0 2003

510(k) Summary

June 4th 2003

1 Submitter

Cryomedical Instruments ltd
Cryomed House
Grove Way
Mansfield Woodhouse
Mansfield
Nottinghamshire
NG19 8BW
United Kingdom

Contact Person: Mr. Gareth Copping, Technical Director
Tel: +44 1623 424200
Fax: +44 1623 424777
E-mail: gareth.copping@cryomed.co.uk

2 Name of Device

Proprietary Name: CryoStar™ system, comprising:
a) CryoStar™ console
b) CryoStar™ 1mm cryoprobe
d) CryoStar™ 2mm cryoprobe
e) Convenience procedure kit for probe placement

Common Name: Cryoanalgesia System

Device Classification: Cryogenic surgical devices have been placed in Class II as per 21 CFR Regulation Number 882.4250 and assigned the Product Code GXH

3 Predicate Devices

The components of the CryoStar™ system are substantially equivalent to the following legally marketed devices:

K781302	Spembly Lloyd Neurostat
K831963	Cryomedics Neurostat
K854334	Wallach Painblocker WA5000

This statement is based on the similarity of the subject device to the predicate devices in intended use, materials, design and principles of operation.

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4 Device Description

The CryoStar™ system consists of a range of cryoprobes that are used for freezing nerves to block pain by temporary ablation. A console is used to house and control the supply of gas to the cryoprobe and to provide an electrical nerve location device. A footswitch completes the system. A convenience procedure kit for probe placement is also provided as a single use disposable.

In the CryoStar™ system, compressed nitrous oxide or carbon dioxide is directed to the tip of the cryoprobe where it is allowed to expand through a fine annular space. The expansion of the gas to near atmospheric pressure causes cooling by the Joule Thompson effect. The design of the cryoprobes is such that the warmer incoming gas maintains the outer stem of the cryoprobe above freezing temperatures to prevent freezing up the stem of the cryoprobe and unwanted tissue damage. A peripheral nerve stimulator in the CryoStar™ console facilitates the location of the peripheral nerve prior to freezing. Freezing of the nerve fibers creates a block which prevents the conduction of pain. The effect is usually non-permanent, and a repeat of the treatment may be necessary to deal with long term pain.

The CryoStar™ console has been designed to provide a simple user interface, together with a series of error detection and warning systems to ensure proper operation. The pedestal of the console provides a convenient small footprint mobile base for the system, and houses up to four gas tanks. A simple footswitch completes the system.

5 Intended Use

The CryoStar™ system is a cryoanalgesia device intended for use in blocking pain by temporarily ablating the peripheral nerves.

6 Summary of Substantial Equivalence

The CryoStar™ system is similar in design, intended use and performance characteristics to the predicate devices. There are now new issues of safety of effectiveness raised by the subject device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 2003

Mr. Gareth Copping
Technical Director
Cryomedical Instruments Ltd
Cryomed House
Grove Way
Mansfield Woodhouse
Mansfield
Nottinghamshire
United Kingdom NG19 8BW

Re: K031482
Trade/Device Name: CryoStar™ Cryoanalgesia System
Regulation Number: 21 CFR 882.4250
Regulation Name: Cryogenic surgical device
Regulatory Class: II
Product Code: GXH
Dated: June 10, 2003
Received: June 25, 2003

Dear Mr. Copping:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Cryomedical Instruments Ltd

510(k) Number (if known): K031482

Device Name: CryoStar™ Cryoanalgesia System

Indications For Use:

The CryoStar™ System is a cryoanalgesia device intended for use in blocking pain by temporarily ablating the peripheral nerves.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031482